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AWARD NUMBER: W81XWH-12-2-0074

TITLE: Checklist and Decision Support in Nutritional Care for Burned Patients

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REPORT DATE: October 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2016	Annual	26 Sep 2015 - 25 Sep 2016

4. TITLE AND SUBTITLE

Checklist and Decision Support in Nutritional Care for Burned Patients

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-12-2-0074

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Our initial Study/Product Aim(s) were as follows: 1) To determine under what conditions compliance with nutritional goals are not met in severely burned adults, 2) To find strategies to address identified gaps in feeding to incorporate into a checklist with easy clinical utility, and 3) To develop and test a system that incorporates the above strategies. The system will provide points in a checklist for provider attention ***and*** decision support guidelines for appropriate changes to meet cumulative and current nutritional goals. In the first year of this award, we have moved forward by collecting data from several hundred severely burned subjects treated in the ICU on nutritional provision from 3 of the 4 centers involved. We have also established the software package upon which the platform will be based. In the coming year, these data will be used to find the gaps in nutritional provision and develop a system to address these through decision support tools.

15. SUBJECT TERMS
Severe burns, nutritional support, decision support

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
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INTRODUCTION

This project was created with the overall goal of producing a decision support tool to assist providers with administering nutritional support to the severely burned, and in particular the severely burned combat casualty. The project was devised in response to a Broad Agency Announcement from the Department of Defence in 2012 soliciting proposals for development and testing of checklists with burn care in the Intensive Care Unit. We submitted this proposal to develop a checklist for the provision of nutritional care which would be supported by decision support technology akin to what we had done previously with burn resuscitation. We initially assembled investigators from 4 Texas burn centers to submit data on nutritional provision in the burn ICU that would be analysed for gaps, and control theory algorithms applied to provide solutions for these gaps. These findings are to be used to develop software technologies to implement recommendations and assist providers in providing nutritional care. We had the following overall hypothesis: **A computerised checklist for the Burn Intensive Care Unit that provides guidelines and information on current and cumulative nutritional provision *and* decision support for subsequent nutritional orders improves compliance with nutritional goals.** We proposed to test this hypothesis through addressing the following *Specific Aims*:

- To determine under what precise conditions compliance with nutritional goals are not met in severely burned adults.

We proposed to gather continuous ICU nutritional data from adult burned patients in four burn centers and assess feeding rates in relation to local nutritional goals with identification of periods of upward and downward variability. These will be correlated to clinical events to ***objectively define incidence and timing of gaps in feeding*** and thus identify targets for improvement.

- To find strategies to address identified gaps in feeding.

After the above analysis we still expect to find gaps during initiation of feeding, during and after expeditions from the ICU for clinical tests and procedures, and in response to periods of higher risk for complications such as high gastric residuals or hypotension. We may also find other unexpected gaps which will be included in further analyses. We then propose to model and report the biologic responses to changes in feeding during these times to find safe strategies to meet calculated feeding rates, and determine safe times to temporarily increase feeding above usual goal rate to close measured gaps.

With completion of these two aims, we will be able to construct a checklist of a clinical and physiologic model and then a computerised decision support system that will perform two functions: the first will be to provide a display of current feeding rate, daily cumulative total with and without indexing to daily goals, and hospital stay cumulative total with and without indexing to cumulative goals. This will serve as a traditional checklist for nutritional provision for the severely burned. Second, the system will provide hourly recommendations for feeding rate to meet provider entered nutritional goals based upon biologically confirmed models and predictions. This is described in our third aim:

- To develop and test a system that incorporates the above strategies. The system will provide points in a computerised checklist for intermittent provider attention *and* decision support guidelines for appropriate changes to meet cumulative and current nutritional goals.

These aims are encapsulated in the following revised *Statement of Work*:

Background: Activity in the burn intensive care unit (BICU) is complex, variable, and can be difficult to coordinate towards the overall goal to improve outcomes. Relatively new technologies are available to assist providers with monitoring critical care activities to be aware of physiologic and treatment changes as well as provide recommendations meet these changes to reach desired goals. One such area in the BICU is in the area of nutrition; providers are in universal agreement to the advisability of feeding to meet nutritional goals, but in spite of this, only 70-80% of goals are typically met. This is thought to be due to temporary interruptions to decrease the risk of complications or to meet other goals. Further, providers are often unaware of

accumulating deficits over the hospitalisation, and if recognised need safe and effective strategies to temporarily accelerate feeding to meet goals.

Objective: To develop and implement a checklist with a decision support system to inform BICU providers of nutritional provision in relation to goals and provide a safe strategy to meet desired nutritional provision.

Project Breakdown:
TASK ONE: After award of funding, we sought administrative approval for data collection of hourly nutritional delivery and associated feedback variables until enrollment goals are reached at the 4 study centers. Due to issues at one of the centers, they elected not to participate (USAISR). Since they were not involved in the funding of the study, this has no repercussions other than the data to develop the model will be less. Additionally, we encountered some difficulties in the approval process which have been alleviated through a significant change in plans to gather the data for model development. We are still seeking approval for the use of existing data that we have from **3 burn centers** (UT-Southwestern, UTMB, and UT-Houston) paid for from the PI through local IRB processes. We already have this data in hand, and that received from UTMB and UT-Houston are de-identified, and were approved locally for collection from their respective IRBs. Thus, these grant funds have not been used to gather this data. This is the *first set of data* that will be used to develop the model. We are still awaiting HRPO approval to use this data for model development (Task 2). In addition, to further add to the data and improve the model, we would still like to gather more data (*second set of data*) from the **3 current burn centers**. Thus, we plan to go through a *second and independent IRB and HRPO approved* process to gather additional data. We have not begun this process until HRPO approval is obtained for analysis of the first set of data. This would remain in task 1, and we expect this will take another 3 months after which we will have the data set for analysis. The *first set of data* has been validated, and the subsequent data will go through the same process.

TASK TWO: Once the data are codified, these will be used to develop a physiologic model of feeding and associated responses across time in severely burned patients. From this model, a checklist and decision support system will be constructed to give providers a real-time assessment of progress towards nutritional goals as well as recommendations for changes in feeding based on model predictions to reach and maintain goals. **TO BEGIN ONCE APPROVALS ARE OBTAINED.**

SUBTASK 1: Complete clinical data analysis for assessment of modern nutrition
SUBTASK 2: Complete clinical data analysis for risks of nutrition in the burn centre
SUBTASK 3: Complete construction of decision support tool and validate with the current database

TASK THREE: Once constructed, the Burn Nutrition and Decision Support System (BNS) will be tested for reliability in a crossover design to assess feasibility, reliability, safety, and efficacy. This study will be performed under another separate and distinct IRB/HRPO approved protocol. The final product will then be available for patent and FDA testing. **TO BEGIN ONCE A MODEL IS DEVELOPED IN TASK TWO**

SUBTASK 1: Obtain IRB and HRPO approval to gather data
SUBTASK 2: Assess pilot use of the decision support device for use of the recommendations, effects of the recommendations on the provision of nutritional therapy, and assessment of use by nursing and physician staff

KEYWORDS

Nutrition, severe burn, decision support

OVERALL PROJECT SUMMARY

TASK ONE: We received IRB approval for collection of data at University of Texas – Southwestern Medical Center, University of Texas Health Science Center – Houston, the University of Texas Medical Branch in Galveston, and at the United States Army Institute of Surgical Research, and then we completed collection of 100 subjects at UT-Southwestern, 42 at the University of Texas Health Science Center – Houston, and 100 at

the University of Texas Medical Branch in Galveston. These data will serve as the initial data for analysis after approval for the analysis from HRPO. We will add more data from these three clinical sites under a separate protocol approved by the respective IRBs and HRPO. We have analysed the first set of data for reliability and reproducibility; less than 1% of entries were adjusted, therefore we feel that these data are accurate and a full audit is superfluous. The preliminary results are as follows:

Two-hundred forty-two subjects were included. Median age was 41 [25,56], TBSA burned 37% [24,55], full thickness burn area 20% [8,43], 31% had inhalation injury. Admission weights were 79 kg [66,94], and discharge weights 70 kg [63,81]. Average weight loss during the hopsitalisation was 7 kg [-15,-2] and percentage loss from admission weight was 9% [-17,-3]. Tube feedings were started on the day of admission in 43%, and within one day of admission in 78%; < 12% were started more than 48 hours from admission. Duration of tube feedings was 18 days [10,30] for this population; ICU days with tube feedings given was 91% [64,100], and for the whole hospitalisation was 67% [44,91].

We are awaiting HRPO approval to use this *first set of data* for analysis. We also plan to gather a *second set of data* to further improve the model which will begin once approval is obtained.

TASK TWO:

Once data are available for analysis, we will proceed assessment to answer the following questions: when did the feeding deficits occur? Were more deficits associated with greater weight loss? Longer hospitalisation? Mortality? We expect this analysis to be complete in Q1 2015 and will be submitted for presentation and publication in a major journal. Portions of the work have already been presented locally (please see the attached PowerPoint presentation to be given in Houston at the Southern Region of the American Burn Association Meeting in November), and two abstracts were presented at this year's meeting of the American Burn Association.

We are also using the data to determine whether any risks were encountered in the process of tube feedings. What about infections? Aspiration? Residuals and subsequent problems? We expect that this will be a separate analysis and publication, and will inform the development of the clinical tool in terms of safety.

Our plan for the next six months is to obtain approval and complete data analysis and assessing the clinical data and outcomes for a description of 'Nutrition and Nutritional Outcomes in the Modern Burn Center'. These data from the two separate protocols are more than sufficient for this purpose. The data to date are de-identified in a single file which will be used for all further work; the original data will be kept separate on a single locked computer; it is not available remotely.

For development of the model, we are currently in negotiations with a local engineering firm to produce the model which will proceed once the data collection is complete.

TASK THREE: Awaiting final product prior to testing. We expect that the tool will be completed and test-worthy in 6 months. During development, we will begin obtaining IRB approval for the single center rollout of the tool.

KEY RESEARCH ACCOMPLISHMENTS

- Data collection performed not funded through this protocol is completed. All data have been analysed for reliability, and found to be accurate. Initial analysis has been performed showing significant weight loss in this population. Two abstracts have been presented and one manuscript prepared (see attached).
- Initial negotiations with an engineering firm to produce the model.

REPORTABLE OUTCOMES

See attached presentation and manuscript.

CONCLUSIONS

We have successfully started the study with revision of the plan and requests for data analysis and further data collection submitted at the local level. These will be approved at the HRPO level prior to further collection and analysis. We have also begun construction of the checklist and decision support tool which we expect to be completed in 6 months. We will then proceed with clinical testing.

Checklist and Decision Support in Nutritional Care for Burned Patients
Proposal Number: 12340011
W81XWH-12-2-0074

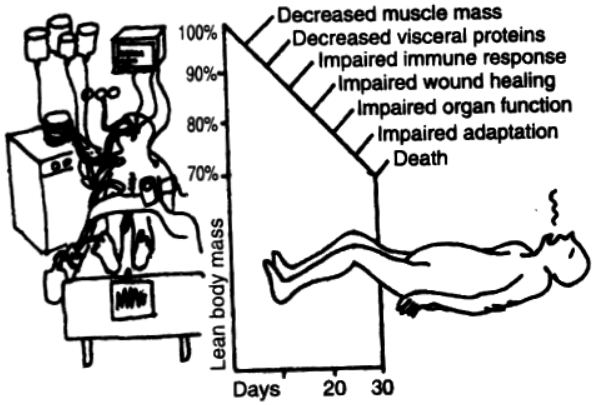
PI: Steven E Wolf, MD **Org:** University of Texas – Southwestern Medical Center **Award Amount:** $498,748

Study/Product Aim(s)

- To determine under what conditions compliance with nutritional goals are not met in severely burned adults
- To find strategies to address identified gaps in feeding to incorporate into a checklist with easy clinical utility
- To develop and test a system that incorporates the above strategies. The system will provide points in a checklist for provider attention *and* decision support guidelines for appropriate changes to meet cumulative and current nutritional goals

Approach

Multicentre prospective study from 3 burn centres to gather data on nutritional provision; downward variance will be assessed and a system devised to minimise these episodes. The system will then be tested for utility. Major burns are present in combat casualties, and recommended nutrition is only given 70-80% of the time. This system will alleviate these deficiencies and improve outcomes.



Data collection complete at all sites (UT-Southwestern, UT-Houston, UTMB, USAISR. Data auditing completed and less than 1% of entries were modified, thus the data set is complete. Second level review being sought for further approval before continuing analysis.

Timeline and Cost

Activities FY	13	14	15	16
Data collection				
Data auditing				
Model development				
Checklist and system clinical testing				
Estimated Budget ($K)	$75	$239	$186	

Updated: 31 Oct 2016

Goals/Milestones

CY12/13 – Project Initiated
✓ Model Development Begun
CY14 – Data Collection
✓ Data Collection Continuing
CY15 – Data Collection
❑ Data Collection Continuing
CY16
❑ Data Collection Continuing
❑ Data Collection Complete and Validated
❑ Model Completed
❑ Clinical Testing

Budget Expenditure to Date

Projected Expenditure: $ 294,368
Actual Expenditure: $ 147,248 (as of 31-12-2014)